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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,489	07/25/2006	Yosuke Funakoshi	Q94183	9109

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
06/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,489	FUNAKOSHI ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-21,24-27,29,30 and 32-35* is/are pending in the application.

4a) Of the above claim(s) *17-21,24-27,30 and 32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-16,29 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/3/06* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of March 12, 2010 made to the office action filed October 14, 2009. Claims 1, 6-21, 24-27, 29, 30 and 32-35 are pending. Claims 1 and 35 are amended, and claims 17-21, 24-27, 30 and 32-34 are withdrawn.

In light of the amendments, the 35 U.S.C. 112, first paragraph rejections over claims 1, 2 and 4 is withdrawn.

In light of the amendments and further considerations the previous 35 U.S.C. 102(b) is now a 103(a) rejection.

Due to the new rejection and drawing objection that was not required by the amendment to the claims, the office action below constitutes a NEW-NON-FINAL action. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the difference between the "3-4" group and the "5" group in the Glasgow Outcome Scale as described in the specification. Particularly, the color of the "3-4" and the "5" group is

the same, so they can not be distinguished from each other. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(1) Claims 1, 6, 7, 9-16, 29 and 35 are rejected under 35 U.S.C. 103(a) as being obvious over Tateishi et al. (Journal of Cerebral Blood Flow & Metabolism, June 2002, vol. 22, no. 6, pp. 723-734).

Using the permanent middle cerebral artery occlusion (pMCAO) model in rats, Tateishi et al. show that there is a significant increase in the infarct volume between 24 and 168 hours after pMCAO, which closely resembles the time course of infarct expansion in human stroke (see page 723, column 2, paragraph 2). Tateishi et al.

teach that (R)-(-)-2-propyloctanoic acid (ONO-2506) leads to mitigation of delayed infarct expansion and early improvement of neurologic deficits (i.e. treatment of cerebral infarction; see title; addresses claims 1, 29 and 35). ONO-2506 also significantly reduced the expression of S-100β (see abstract, lines 3-4 and 11-12; addresses claim 16). The rats were administered intravenously 1mg/kg, 3 mg/kg or 10mg/kg daily, in which significantly reduced the infarct volume at 168 hours (i.e. continuous intravenous administration for 7 days; 700 mg if an average human at 70 kg; 3 mg if a rat at 300 g or 0.3 kg; see page 725, column 1, determination of the optimal dose of ONO-2506 experiment 1; Figure 1; and page 727, column 1, the therapeutic time window of ONO-2506: experiment 4; addresses claims 1, 6, 7, 9-15 and 35).

Tateishi et al. does not specifically teach the range of between about 100 mg to about 2,100 mg of (2R)-2-propyloctanoic acid.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Tateishi et al. and the claimed range amounts because Tateishi et al. teach the administration of (R)-(-)-2-propyloctanoic acid (ONO-2506) to a rat intravenously 10mg/kg daily significantly reduced the infarct volume at 168 hours (see page 725, column 1, determination of the optimal dose of ONO-2506 experiment 1 and page 727, column 1, the therapeutic time window of ONO-2506: experiment 4). Thus, if one were to administer the same compound at 10mg/kg to a human at 70 kg, one would administer 700 mg, which is within the range. It is

noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

(2) Claim 8 is rejected under 35 U.S.C. 103(a) as being obvious over Tateishi et al. (Journal of Cerebral Blood Flow & Metabolism, June 2002, vol. 22, no. 6, pp. 723-734) as applied to claims 1, 6, 7, 9-16, 29 and 35 above in view of Shirasaki et al. (US 5,837,706).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Tateishi et al. are as applied to claims 1, 6, 7, 9-16, 29 and 35 above.

Tateishi et al. does not specifically teach that the continuous inravenous administration is from an infusion bag.

Shirasaki et al. teach that a drug that treats cerebrovascular disorders such as cerebral infarction is preferably administered by intravenous drip infusion (i.e. infusion bag administration; see column 4, lines 44-47 and column 5, lines 7-9).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine use an infusion bag administration in the method of Tateishi et al. because Shirasaki et al. teach that cerebrovascular disorders such as cerebral infarction is preferably treated through the intravenous drip infusion administration route (i.e. infusion bag administration; see column 4, lines 44-47 and column 5, lines 7-9).

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627